09/351149

PEREGRINE
Pharmaceuticals, Inc.

CZJ

WRITER'S DIRECT DIAL:
(713) 439-0108

November 17, 2006

Temp. Ref.: 3999.002383

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Alexandria, VA 22313-1450

CERTIFICATE OF MAILING
37 C.F.R. § 1.8

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November 17, 2006
Date

Sharon V. Hart
Sharon V. Hart

RE: U.S. Patent No. 7,067,109; Entitled "Cancer Treatment Kits Comprising Therapeutic Conjugates That Bind to Aminophospholipds"; by Thorpe, Ran and Brekken; U.T. Ref.: UTSD:0556--2 US; Peregrine Family: UTS05;

Sir:

Enclosed are two originals of the form PTO-1050. Errors of a minor nature are thereon corrected. The errors are due to Patent Office oversight. Correction of the errors in the documents cited by the examiner, which need to be marked *, is supported by the Office Actions dated November 7, 2000, March 13, 2001, December 31, 2001; and July 15, 2003 (copies attached).

A Certificate of Correction is requested under 35 U.S.C. § 254. Although no fees should be required, should any fee under 37 C.F.R. § 1.20(a) be required for any reason, the Commissioner is authorized to deduct said fee from Peregrine Pharmaceuticals, Inc. Deposit Account No. 50-3493/3999.002383.

Please date stamp and return the enclosed postcard to evidence receipt of these materials.

Respectfully submitted
PEREGRINE PHARMACEUTICALS, INC.
CUSTOMER NO. 000052101

Shelley P.M. Fussey, Ph.D.
Reg. No. 39,458
Agent for Applicants

Certificate
NOV 28 2006
of Correction

Encl.

NOV 28 2006

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PTO/SB/44 (04-05) Approved for use through 04/30/2007. OMB 0651-0033
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

(Also Form PTO-1050)

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 7,067,109

APPLICATION NO.: 09/351,149

ISSUE DATE : June 27, 2006

INVENTOR(S) : Philip E. Thorpe, Sophia Ran and Rolf A. Brekken

It is certified that errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Title page, item (56), column 1, after "4,867,962 A" and before "9/1989 Abrams. . . . . 424/1.1", insert --*--.

At page 2, column 1, after the reference "6,036,955 A" and before "3/2000 Thorpe et al. . . . . 424/136.1", insert --*--.

At page 2, column 1, after the reference "6,051,230 A" and before "4/2000 Thorpe et al. . . . . 424/178.1", insert --*--.

At page 2, column 1, after the reference "6,312,694 B1" and before "11/2001 Thorpe et al. . . . . 424/178.1", insert --*--.

At page 2, column 1, after the reference 2003/0194400 A1 10/2003 Liu et al. . . . . .424/94.64", insert --Serial No. 09/351,862 Thorpe et al.--.

At page 2, column 1, after the reference "WO WO98/29453 7/1998", insert --*--.

At page 2, column 2, after the reference "Fishman et al., "Autoimmunity and Cancer-Beneficial Relationships: a new Concept for the Production of Human Monoclonal Antibodies (Review)," *International Journal of Oncology*, 10:901-904, 1997." insert --*--.

At page 5, column 1, after the reference "Umeda et al., "Effective Production of Monoclonal Antibodies Against Phosphatidylserine: Stereo-Specific Recognition of Phosphatidylserine by Monoclonal Antibody", *J. Immunol.*, 143:2273-2279, 1989", insert --*--.

MAILING ADDRESS OF SENDER (Please do not use customer number below):

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PTO/SB/44 (04-05) Approved for use through 04/30/2007. OMB 0651-0033
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Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/351,149	07/12/99	THORPE	P 4001.002383

HM12/1107

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EXAMINER	
SHAREH, S	
ART UNIT	**PAPER NUMBER**
1619	13

DATE MAILED: 11/07/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-9, 16-19, 24-32, 43 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim1-49 of U.S. Patent No. 6,036,955, claims 40-61 of U.S. Patent No. 6,051,230. Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of both the instant claims and the patented claims overlap. In the instant case both set of claims are directed to kits comprising a at least one targeting agent-therapeutic agent directed to an amino phospholipid, and at least a second targeting agent-therapeutic agent specific to coagulation of the tumor vasculature by delivery of a coagulant.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1-9, 16-19, 24-32, 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Huang et al, *Science* 275:547-550,1997 in view of Martin US Patent 6,043,094.

The instant claim is directed to combination of a targeting agent-therapeutic agent construct, a targeting agent-detectable agent construct and at least a second anti-cancer agent.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/351,149	07/12/99	THORPE	P 4001.002383

HM22/0313

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ART UNIT	**PAPER NUMBER**
1619	16

DATE MAILED: 03/13/01

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Commissioner of Patents and Trademarks

7. Applicant's arguments with respect to the rejection of claims 1-9, 16-19, 24-32, 43 under 35 U.S.C. 103(a) as being unpatentable over Gimbrone et al US Patent 5,632,991 in view of Huang et al *Science* 275:547-550,1997 have been fully considered and are found persuasive. This rejection is withdrawn. Applicant's arguments with respect to the rejection of claims 1-9, 16-19, 24-32, 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gimbrone et al US Patent 5,632,991 in view of Dvorak et al, *Cancer cells*, 1991: 3(3); 77-85 have been fully considered and are found persuasive. This rejection is withdrawn.

Applicant's remarks with respect to the prosecution of the co pending application Serial No. 09/351,457 has been noted. The prosecution of this application is independent of its co pending counter part.

New Grounds of rejection

8. Claims 1-9, 16-19, 24-32, 43, 45-48 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation of "a second anti cancer agent" in claim 1 is vague. It is not clear to what second anticancer agent is applicant referring. The recitation of "a second anti cancer agent" lacks antacedent basis.

9. Claims 1-9, 16-19, 24-32, 43, 45-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blankenberg et al US patent 6,197,278 in view of Haung et al Science 275: 547 - 550 1997, and further in view of WO 98/29453('453) (IDS 1/24/2000), Fishman et al (IDS 2/14/2000).

phophatidylserine on the outer cell membrane such as squamous cell carcinoma of the skin (page 903).

Although Blackenberg does not teach the use of a second anti-cancer agent in their imaging or therapeutic methods, it would have been obvious to one of ordinary skill in the art at the time of invention to combine the teachings of Blackenberg, and Haung to enhance the antivascular therapy of a solid tumor of interest, because Blackenberg suggests that his methods can be used for both therapeutic and imaging purposes, and Haung suggests that specific targeting of the tumor cell surface markers with bispecific antibodies such as those directed to MHC class II can significantly improve the efficacy of coaguligand therapy. Fishmann and WO '453 complement the teachings of Blackenberg and Haung because they show the general state of art form preparing peptide drugs and autoantibodies directed to aminophospholipids, thus, preparing such conjugates in combination or alone would have been obvious. Finally, preparing a convenient therapeutic kit for a clinical setting containing the essential components of such therapy would have been well within purview of an ordinary practitioner and thus obvious at the time of invention.

now 6,312,694

10. Claims 1-9, 16-19, 24-32, 43-48 are provisionally rejected under the judicially created doctrine of double patenting over claims 1-10 of copending Application No. 09/351,457. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/351,149	07/12/1999	PHILIP E. THORPE	4001.002383	9329

7590 12/31/2001

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ART UNIT	PAPER NUMBER
1619	

DATE MAILED: 12/31/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Claim R jections - 35 USC 103

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

18. Claims 1-9, 16-19, 24-31, 43, 45-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schroit US Patent 6,300,308 in view of Gimbrone US Patent 5,632,991, Blackenberg et al US Patent 6,197,278, and Umeda (IDS, 9/19/1999). (*)

The teachings of Schroit are discussed above. Schroit teaches that various known techniques may be used to prepare more specific antibodies. Further, Schroit elaborates that various types of antibodies such as humanized mAbs, or murine modified antibodies may be used for his methods (see col 4, lines 38-49;

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/351,149	07/12/1999	PHILIP E. THORPE	4001.002383	9329

23720 7590 07/15/2003

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EXAMINER
SHARAREH, SHAHNAM J

ART UNIT	PAPER NUMBER
1617	39

DATE MAILED: 07/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 07-01)

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-9, 16-19, 24-31, 45-57 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Schroit US Patent 6,300,308 in view of Gimbrone US Patent 5,632,991, Blackenberg et al US Patent 6,197,278 and Abrams US Patent 4,867,962.

Schroit teaches that various known techniques may be used to prepare more specific antibodies. Schroit elaborates that various types of antibodies such as humanized mAbs, or murine modified antibodies may be used for his methods (see col 4, lines 38-49; col 13, lines 24-55). Schroit, however, fails to specifically disclose the use of other suitable antiphospholipid antibodies in combination with a second anticancer agent conjugated with a targeting antibody.

Gimbrone discloses targeting agents conjugated to an antibody directed to ELAM-1 (E-Selectin), (col 5, lines 18-38). Gimbrone teaches that such endothelial specific adhesion molecules are rapidly unregulated on the surface of cultured human vascular endothelial cells (col 27, lines 59-67). Gimbrone also discloses the use of his targeting agent-therapeutic agent conjugate, alone or in combination with other antibody or antibody fragment and/or a therapeutic agent (a second anti-cancer agent) (col 15, lines 46-55). Therapeutic agents of Gimbrone produce apoptosis as they encompass various toxins, antioxidants and anti-tumor drugs (see col 12-14, claim 2). Finally Gimbrone teaches that E-Selectin or a leukocyte-binding fragment thereof can be coupled to a chemotherapeutic drug that binds to tumor cell expressing receptors for E-Selectin, to kill the tumor cell (col 13, lines 58-67). Gimbrone also disclose methods for

to target a specific site is well established in the art. Therefore, the claims that require no more than mixing together two conventional anti-tumor agents set forth prima facie obvious subject matter and as indicated by Abrams, the ordinary skill in the art would have had a reasonable expectation of success in targeting cancerous regions.

Double Patenting

Claims 1-9, 16-19, 24-32, 43, 45-49 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over pending claim of copending Application No. 09/351862. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are both directed to kits comprising antibodies directed to aminophospholipids.

Applicants arguments with respect to the provisional double patenting rejection that exists in Sn 09/351,862 have been noted but are not relavent here, because prosecuion of SN 09/351,862 ('862) is separate from the instant application. Applicants further appear to argue that the pending application should contain a double patenting rejection over the co-pending application 09/351,149. In response, Examiner states that the purpose of a provisional double patenting rejection is to place Applicant on proper notice about the overlapping nature of the claimed subject matter. It appears that Applicant has properly been served of such notice to maintain the co-pending claims patentably separate. Nevertheless, to the extent it is relavent, Examiner points out that the claims in this application are generic to the the instant pending claims. The generic claim of this application may not necessarily render the instant species claims obvious.